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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,257	12/14/2001	Jangbir S. Sangha	CHO004/106011	8707

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/020,257	SANGHA ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-25,40-55,66,68-73,75,76,78-83,85,86,88-93 and 95-102* is/are pending in the application.

4a) Of the above claim(s) *7-25,40-55 and 96-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66,68-73,75,76,78-83,85,86,88-93 and 95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status

1. Claims 7-25, 40-55, 66, 68-73, 75, 76, 78-83, 85, 86, 88-93, 95-102 are pending.

Claims 66, 68-73, 75, 76, 78-83, 85, 86, 88-93, 95 are rejected.

Claims 7-25, 40-55, 96-102 are withdrawn from consideration.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 66, 69, 73, 75-76, 79, 83, 85-86, 89, 93 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al (U.S. Patent 2,703,083).

As applicant is aware, a product need not share the same intended use in order to anticipate a claim. As MPEP 2114 notes, for example, "A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim." This rejection, using the Gross reference, meets the structural limitations of the claim.

Gross teaches a device of claims 66, 76, 86 comprising:

(a) a collection portion (see figure 4 and column 6, lines 55-60, where either the dressing pad of the adhesive bandage or the actual adhesive portion (often referred to using Johnson and Johnson's trademarked name Bandaid ®) will function to collect material, and in particular, will ordinarily collect blood, where blood is clearly a material containing DNA),

The collection portion has a front and rear surface, with the rear surface having a covering thereon to prevent collection of material containing DNA and the front surface is available for collection of material containing DNA (see figure 4, where the dressing pad 42 is placed on a sheet 40 that may be composed of a nonporous material such as plastic and where an adhesive layer 41 is also placed on sheet 40 (see column 10, lines 26-36, for example) where the pad is exposed to the wound on the front surface and the adhesive layer is attached to skin but the rear surface is covered as in a normal adhesive bandage),

(b) a housing for holding said device (see column 11, example 1, lines 41-44, where the adhesive bandages were wrapped in glassine paper that was sealed, where the glassine paper is a housing),

(c) a treatment applied to said housing after said housing is filled with said device, said treatment comprising an effective quantity of an agent for disabling DNA from interfering with subsequent speciment specific DNA analysis (see column 11, lines 60-70, where ethylene oxide treatment was used to sterilize the bandages).

With regard to claims 69, 79, 89, Gross teaches ethylene oxide treatment was used to sterilize the bandages (see column 11, lines 60-70).

With regard to claim 66, 76, 86, Gross teaches a second protective layer that is foldable over the second side to prevent contamination of the second side which may even form a pouch (see figure 4, where the plastic covers of the adhesive also cover the pad and are foldable over the dressing pad 42 and see figures 9 and 10 for pouchlike form).

With regard to claim 73, 83, 93, Gross teaches a dressing pad composed of paper (see column 6, line 55).

With regard to claims 75, 84-85, 95, Gross teaches an adhesive surface which is variable since the adhesive properties of the dressing pad 42 are lower than the adhesive properties of the adhesive layer 41 (see column 6, lines 6-21 and figures 1-4, for example).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 68, 70-71, 78, 80-81, 88 and 90-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al (U.S. Patent 2,703,083) in view of Northview Biosciences Inc. (March 2001) (titled Sterility Assurance Compliance) (http://www.northviewlabs.com/pdf_docs/SterilityAssurance.pdf).

Gross teaches a device of claims 66, 76, 86 comprising:

(a) a collection portion (see figure 4 and column 6, lines 55-60, where either the dressing pad of the adhesive bandage or the actual adhesive portion (often referred to using Johnson and Johnson's trademarked name Bandaid ®) will function to collect material, and in particular, will ordinarily collect blood, where blood is clearly a material containing DNA),

The collection portion has a front and rear surface, with the rear surface having a covering thereon to prevent collection of material containing DNA and the front surface is available for collection of material containing DNA (see figure 4, where the dressing pad 42 is placed on a sheet 40 that may be composed of a nonporous material such as plastic and where an adhesive layer 41 is also placed on sheet 40 (see column 10, lines 26-36, for example) where the pad is exposed to the wound on the front surface and the adhesive layer is attached to skin but the rear surface is covered as in a normal adhesive bandage),

(b) a housing for holding said device (see column 11, example 1, lines 41-44, where the adhesive bandages were wrapped in glassine paper that was sealed, where the glassine paper is a housing),

(c) a treatment applied to said housing after said housing is filled with said device, said treatment comprising an effective quantity of an agent for disabling DNA from interfering with subsequent speciment specific DNA analysis (see column 11, lines 60-70, where ethylene oxide treatment was used to sterilize the bandages).

With regard to claims 69, 79, 89, Gross teaches ethylene oxide treatment was used to sterilize the bandages (see column 11, lines 60-70).

With regard to claim 66, 76, 86, Gross teaches a second protective layer that is foldable over the second side to prevent contamination of the second side which may even form a pouch (see figure 4, where the plastic covers of the adhesive also cover the pad and are foldable over the dressing pad 42 and see figures 9 and 10 for pouchlike form).

With regard to claim 73, 83, 93, Gross teaches a dressing pad composed of paper (see column 6, line 55).

With regard to claims 75, 84-85, 95, Gross teaches an adhesive surface which is variable since the adhesive properties of the dressing pad 42 are lower than the adhesive properties of the adhesive layer 41 (see column 6, lines 6-21 and figures 1-4, for example).

Gross does not teach modes of sterilization other than ethylene oxide.

Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2), addressing the limitations of claims 68, 70-71, 78, 80-81, 88 and 90-91.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to sterilize the bandages of Gross using any of the known means taught by Northview Biosciences since Northview Biosciences notes "Sterility is essential to the safety of many medical devices. Most single use devices are terminally sterilized by ethylene oxide gas or gamma or electron beam radiation (see page 2)". An ordinary practitioner would have been motivated to sterilize using known equivalent methods of sterilization in order to ensure that the single use bandages are terminally sterilized. Further, MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)." Here, the different modes of sterilization are expressly recognized by the prior art as known equivalents for the same purpose.

7. Claims 66, 68-73, 75, 76, 78-83, 85, 86, 88-93 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricciardi et al in view of Furcht et al (U.S. Patent 6,303,288) in view of Northview Biosciences Inc. (March 2001) (titled Sterility Assurance Compliance) (http://www.northviewlabs.com/pdf_docs/SterilityAssurance.pdf).

Ricciardi et al teaches a kit for the collection of material containing DNA (see abstract and figure 1) comprising:

(a) a housing containing at least one collection device for collection material containing DNA (see figure 1 and column 2, lines 30-42).

Ricciardi expressly teaches that the swabs may be used for PCR amplification and that the swabs should be sterile (see column 2, lines 5-10).

With regard to claims 75, 85, 95, Ricciardi teaches the use of Dacron swabs which have some level of adhesion that is variable in it's binding (see column 3, lines 36).

Ricciardi et al does not teach modes of sterilization.

Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2)

With regard to claims 76 and 86, Ricciardi teaches placement of the swabs in a protective pouch (see figure 1).

With regard to claims 68-71, 78-81, 88-91, Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2)

Ricciardi et al in view of Northview Biosciences Inc. do not teach a device which has a rear surface that prevents collection of the DNA.

Furcht et al teaches, with regard to claims 66, a device for the collection of material containing DNA (see abstract and figure 1) comprising:

A device for collecting material containing DNA that has a collection portion, (figure 3, reference number 32, which column 8, lines 54-67 identifies as a sample collection pad that is placed on a plastic support, reference number 31 (see column 8, lines 41-44), where the figure shows a front surface that is available for the collection of material containing DNA and a rear surface that is covered by plastic and is not available for DNA collection (see figure 3).

With regard to claims 72, 73, 75, 82, 83, 85, 92, 93, 95, Furcht teaches the use of FTA paper which inherently has some level of adhesion that is at least slightly variable in it's binding (see column 8, line 58).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the device of Furcht in the kit of Ricciardi since Furcht notes "This application of the microcantilever based sensor offers superior sensitivity, specificity and utility in an integrated MEMS system format (see column 12, lines 7-10)." Furcht further motivates the use of FTA paper by noting "DNA extractions on FTA^{tm} paper have demonstrated significant ease in use and reduced cost in

performing routine clinical molecular genetic testing (see column 2, lines 53-56)." Motivation to sterilize the device is provided by Northview Biosciences which notes "Sterility is essential to the safety of many medical devices. Most single use devices are terminally sterilized by ethylene oxide gas or gamma or electron beam radiation (see page 2)". An ordinary practitioner would have been motivated to use the device of Furcht in the kit of Ricciardi since the device will improve sensitivity, specificity and utility and reduce labor costs and specimen sizes (see column 12 and column 2, lines 21-38). Further, an ordinary pracititioner would have been motivated by Northview biosciences to sterilize the kit in order to improve the safety of the device and to ensure that swabs, which would be placed within the oral cavity of human beings, would not contain any hazardous materials such as pathogenic microorganisms or viruses.

Response to Arguments

8. Applicant's arguments filed January 8, 2007 have been fully considered but they are not persuasive.

Applicant argues that the Gross bandage lacks an adhesive surface on the "collection substrate". While Applicant correctly notes that the dressing pad is not intended to function as an adhesive, it is equally certain that the dressing pad has some level of adhesive properties. However, this is not necessary for the rejection. The bandage of Gross expressly comprises an adhesive layer 41 on the same side of the bandage as the dressing pad. This adhesive layer expressly meets the "adhesive surface" requirement of the claim. The difference in intended uses does not distinguish this product claim from the product of Gross. That is, the product of Gross, comprises

the adhesive layer for the purpose of adhering the bandage adjacent to the wound surface. However, this adhesive layer will still collect DNA containing material. The clearest evidence of this is the common experience of having hair pulled out that remains affixed to the adhesive surface of Bandaids ®. This hair is DNA containing material. Therefore, the bandages of Gross remain anticipatory as discussed in the rejection and the rejection is maintained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey Fredman
Primary Examiner
Art Unit 1637
2/15/07